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| 09/910,703      | 07/20/2001  | Bruce J. Barclay     | VASC 1020-2         | 2083             |

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

DATE MAILED: 06/25/2003

65

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/910,703

Applicant(s)

BARCLAY ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3,4,8,9,11,19-23,25-27,38-43,45-57,59-62,74-78 and 101-107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4,8,9,11,19-23,25-27,38-43,45-57,59-62,74-78 and 101-107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3,4,8,9,11,19-23,25-27,38-42,74-78,101-105,107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 38 and 74, the active agent is on "at least one of said inner surface of the material and within the sleeve interior" which is unclear because it is not understood how a material can have more than one inner surface. The use of "at least one of" implies there can be more than one and since this recitation is before the inner surface, it makes the claim ambiguous. It is the Examiner's understanding that the sleeve interior and inner surface encompass the same area.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,9,26,27,38-41,74-77,101,102 are rejected under 35 U.S.C. 102(b) as being anticipated by Razavi (5676685). Figs. 11 and 13 show a coiled body 12 with radially extending openings between the adjacent rings. Claims in a pending application are given their broadest reasonable interpretation, In re Hyatt, 211 F.3d 54 USPQ2d 1664 (Fed. Cir. 2000). In this instance it can be construed that the material 14 extending along the coiled path there is a material forms a coiled sleeve. Since this

Art Unit: 3738

material **14** contains the coiled body **12** it is a sleeve, see Fig. 2 showing that the coil **12** is surrounded by material **14**. Razavi discloses that an anti-thrombotic drug is associated with the material, col. 3, lines 22-25. Fig. 2 shows that a delay-release material or biodegradable layer **16** is used on the material with the drug, col. 3, lines 12-17. Razavi also discloses the body or core coil is made of metal, col. 2, lines 37-47. Razavi additionally discloses a sheath or sleeve can be the protective layer and pulled off upon deployment, col. 6, lines 13-16. Regarding claims 41,45,77, Figs. 8 and 10 show the prosthesis with spaced apart turns defining gaps in the radially expanded state. Fig. 1 shows the sleeve following the coil body and thus has regions occupied by the coiled body and open spaces not occupied by the coiled body since it is shown as being oversized with the coil in the center of the sleeve.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4,8,19-23,25,38,42, 43,45,47-57,59-62,74,78,103,104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski et al. (WO 97/40755) in view of Kropf (4760849) and Ragheb et al. (5873904). Zukowski et al. disclose (Figs. 15,16) a stent having a coiled body **501** with a porous graft material extending along and completely covering the coiled body. The device is delivered to a site and applied externally to a hollow body structure. Zukowski also discloses the stent body is made of metal, page 9, col. lines 25,26. Zukowski additionally discloses the graft material is ePTFE and can also have a protective layer, page 9, lines 23,24,34,35. Regarding

Art Unit: 3738

claims 25, 54, it is inherent that the inner surface of the porous material is impervious to blood such that the blood vessel does not leak from the prosthetic device being applied thereto. However, Zukowski et al. do not disclose a stent body that has spaced-apart parallel side elements joined by connector elements or an agent in the porous graft material or that the outer covering is biodegradable. Kropf teaches a stent body with spaced-apart parallel side elements joined by connector elements, Fig. 5. Ragheb teaches a drug layer with a porous covering thereon, col. 4, lines 23-32. Ragheb also teaches the drugs that can be delivered via the stent include anti-inflammatories and antiproliferatives or antirestenotic agents, col. 4, lines 60-67. Ragheb additionally teaches the bioactive material or drugs can be microencapsulated, col. 19, lines 60-63. Ragheb teaches the outer porous layer can be a polymer that is biodegradable, col. 13, lines 33-44. Ragheb also teaches the use of first and second dispensable agents, col. 5, lines 58,59,63 and col. 6, lines 3-14. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the device of Zukowski et al. in order to provide a stent with greater structural support and to incorporate a drug such as an anti-inflammatory in the polymer as taught by Ragheb with the stent graft of Zukowski as modified by Kropf in order to locally administer a drug to be absorbed into the vessel through the wall of the vessel.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi '685 in view of McNamara et al. (5147370). Razavi is explained supra. However, Razavi does not disclose the prosthesis comprising turns touching one another when in the expanded state. McNamara et al. show a coil (Fig. 1) with turns touching one

Art Unit: 3738

another when in the expanded state, see also col. 3, lines 55,56. McNamara also teaches the coil is to be designed with closely spaced turns, col. 6, lines 19-23. It would have been obvious to one of ordinary skill in the art to use a closely spaced turned coil as taught by McNamara with the coiled body of Razavi in order to provide more structural support to the vessel.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski et al. (WO 97/40755) in view of Kropf '849 and Ragheb et al. '904 as applied to claim 43 above, and further in view of McNamara et al. '370. Zukowski as modified by Kropf and Ragheb is explained supra. However, Zukowski in view of Kropf and Ragheb do not disclose the turns touching one another when in the expanded state. McNamara is explained as above. It would have been obvious to one of ordinary skill in the art to use a closely spaced turned coil as taught by McNamara with the coiled body of Zukowski as modified by Kropf and Ragheb in order to provide less areas of open space where no stent frame exists. By having the turns closer there is greater support in the areas where the stent is applied.

Claims 43,106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski et al. (WO 97/40755) in view of Kropf '849 and Hanson (5399352). Zukowski as modified by Kropf is explained as before. However, Zukowski in view of Kropf do not disclose the use of an agent to deliver in the vessel such as a NO generator. Hanson teaches a method of locally delivering a substance, such as a NO generator to a site for preventing restenosis, col. 6, lines 3-5,60-64. It would have been obvious to one of ordinary skill in the art to incorporate a NO generator between the porous material and

the covering as taught by Hanson with the stent of Zukowski as modified by Kropf in order to prevent restenosis in the patient while the stent is applied to the vessel.

Claims 105,107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi in view of Hanson '352. Razavi is explained as before. However, Razavi does not disclose the use of a NO generator as the agent. Hanson teaches that NO generators are used to prevent or treat restenosis, col. 6, lines 3-5,60-64. It would have been obvious to one of ordinary skill in the art to use a NO generator as taught by Hanson with the stent of Razavi having a bioactive agent such the NO generator prevents restenosis in the patient while the stent is in the body.

### ***Response to Arguments***

Applicant's arguments filed 4/17/03 have been fully considered but they are not persuasive. In response to the remarks regarding the Razavi reference, it is noted that Fig. 2 shows that material does encase the coil and thus it can be characterized as a sleeve. Applicant failed to submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions with respect to the Edwin or Ragheb patents. Applicant must discuss all the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3738

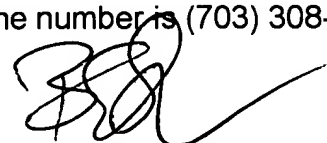
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738  
June 19, 2003

Bruce Snow

Primary Examiner

